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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/314,497 05/19/99 SCHINDLY

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IM22/0703  
THOMAS E KOCOVSKY JR  
FAY SHARPE BEALL FAGAN MINNICH & MCKEE  
1100 SUPERIOR AVENUE  
7TH FLOOR  
CLEVELAND OH 44114

EXAMINER

CHORBAJI, M

ART UNIT

PAPER NUMBER

1744

DATE MAILED:

07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.

09/314,497

Applicant(s)

SCHINDLY ET AL.

Examiner

MONZER R CHORBAJI

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: 2.

Art Unit: 1744

### DETAILED ACTION

**THIS OFFICE ACTION IS IN RESPONSE TO THE AMENDMENT RECEIVED 5/2/01.**

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Critical or essential to the practice of the invention, but not included in the claim is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). With regard to the amended claim 3, "the second peripheral wall having a detachable portion". This is a new matter since it is not supported in the originally filed disclosure.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1744

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minerovic et al (U.S.P.N. 5,997,814) in view of Malchesky et al (U.S.P.N. 5,518,927).

Minerovic et al teaches of a package, col.2, line 12, which can be used in a single application, for holding a powdered composition, col.2, line 12, which forms a solution of an anti-microbial decontaminate when mixed with water, col.2, lines 13-14, and for selectively releasing the composition, col.3, lines 60-62, the package comprising: a porous portion, col.5, lines 63-67, and col.6, lines 33-35; first compartment for receiving a first component of the composition, second compartment for receiving a second component of the composition, col.2, lines 27-30, the porous portion, first compartment, and second compartment configured for forming a fluid flow

Art Unit: 1744

path for the decontaminate solution through the package, col.6, lines 52-60, and col.10, lines 12-27; cartridge or package further includes: outer, first cup, figure 3 (50), including a first peripheral wall, figure 3 (52), with an opening at an end, figure 3 (60), the first peripheral wall being at least selectively water transmissive, col.8, lines 8-17, inner second cup, figure 3 (70), including a second peripheral wall, figure 3 (72), second peripheral wall being at least selectively water transmissive, col.8, lines 24-27, the first and second cups being configured such that the second peripheral wall abuts, figure 4 (74), and is connected to the first cup, figure 4 (54), adjacent the end of the first peripheral wall, figure 4 (52), top cover, figure 4 (94), covering the openings in the first and second cups, such that the first compartment, figure 4 (88), is defined in the first cup, figure 4 (50), and the second compartment, figure 4 (not labeled), is defined in the second cup, figure 3 (70); first peripheral wall includes a region which is formed from a first material, col.9, lines 54-56; first cup peripheral wall includes a side and a base, figure 3 (50, 52, and 60), and wherein the base is detachable from the side, figure 4 (58); second peripheral wall, figure 4 (72), includes a region which is formed from a second material, col.9, lines 56-57, which is impermeable to the first and second components but is permeable to water and to solutions containing dissolved components, col.8, lines 57-62, second peripheral wall defines a hemisphere and is formed from the second material, figure 4 (72); top cover defines the porous portion, col.9, lines 34-35; porous portion is formed from non-woven polypropylene web, col.6, lines 24-27; decontaminate includes peracetic acid, col.7, line 10, first component

includes acetylsalicylic acid and the second component includes sodium perborate, col.10, lines 1-3; well, figure 2 (16), for receiving the package of claim 1, source of water connected with the well, col.5, lines 9-16, for mixing with the powdered composition to form the antimicrobial solution, a microbial decontamination chamber, figure 2 (C), connected with the well for receiving the anti-microbial solution, the well the porous region and the chamber forming a re-circulating fluid flow path for the decontaminate solution, col.4, lines 66-67, and col.5, lines 1-31; package for releasing an antimicrobial composition into a flowing liquid, comprising: side wall, figure 3 (52), having a first opening, figure 3 (56), at a first end, and a second opening, figure 3 (60), at a second end such that the liquid flows through the first opening into the package and out through the second opening, layer of porous material, figure 4 (94), spanning one of the first and second openings such that the liquid flows through the porous material layer, figure 2 (C, 16, 28, 24, 14, and 12), an antimicrobial source is disposed within the package, figure 4 (88), for releasing the antimicrobial composition into the flowing liquid, figure 2 (C, 16, 28, 24, 14, and 12), to form an antimicrobial solution. Minerovic et al further teaches of a method including all the limitations mentioned above, columns 10-12. In addition, Minerovic et al teaches of using measured amounts of the reagents to form the required concentration of the sterilant to effect sterilization, col.2, lines 1-3, and also uses the word "metering" a preselected amounts of both reagents, col.3, lines 24-45, but Minerovic et al does not explicitly mention of a certain range of concentration of the sterilant. Furthermore; Minerovic et al teaches of using a heater, figure 2 (30), to

maintain the circulating sterilant at a certain temperature, but does not explicitly mention of a certain range of temperature.

Minerovic et al does not teach of using an indicator, which exhibits a detectable change on exposure to the decontaminant in the solution.

Malchesky et al teaches of an instrument and a method in the art of sterilizing medical equipment, col.1, lines 6-27, comprising the following: an indicator, col.6, lines 17-18, on the porous portion, col.5, lines 61-62, which exhibits a detectable change, col.2, lines 20-24, on exposure to the decontaminant in the solution, col.3, lines 24-26; indicator includes an oxidizable species, col.2, lines 22-24, on prolonged contact with the solution, col.3, line 61, and col.4, line 3; indicator is specific for the decontaminant, col.3, lines 23-30, peracetic acid is used in the art of sterilization, col.3, lines 26-32, and is used in the preferred embodiment of this prior art along with crystal violet so that a good correlation between the decontaminant and the indicator can be established without the interference of other factors, such as pH, indicator is impregnated into the porous portion, abstract, lines 1-3, in the form of an ink, col.6, lines 37-42, and col.6, lines 13-18; sufficient concentration, col.3, line 64, for a sufficient period of time, col.3, line 61; an indicator provides a detectable color change when peracetic acid is at a concentration of about 900 PPM or above, col.3, lines 62-65, for a preselected period of time; wherein the decontaminant is peracetic acid, col.3, line 63, and the indicator is crystal violet, col.3, line 52; an indicator on the porous material layer which changes color in response to contact with the antimicrobial solution, a degree of color change

varying in accordance with a concentration of an antimicrobial agent and duration, col.5, lines 61-67, and col.6, lines 1-7; examining the indicator for the detectable change, col.6, lines 29-36.

Thus, it would have been obvious and one having ordinary skill in the art would have been motivated to combine the teaching of Minerovic et al for an apparatus and a method of using a package for holding a powdered composition which forms a solution of an anti-microbial decontaminant used the sterilization and disinfection arts with another art-known in the sterilization and disinfection for using an indicator which exhibits a detectable color change as taught by Malchesky et al for the known and expected results of providing an accurate and quick system for maintaining an adequate levels of the sterilant in a decontamination cycle.

### ***Response to Arguments***

7. Applicant's arguments filed April 19, 2001 have been fully considered but they are not persuasive.

With regard to the Minerovic et al patent being not a proper reference under 103(a) / 102(e), please refer to MPEP 706.02 (L) (3) on line version. I have downloaded a copy of the provisions of 103(c) from the MPEP on line version. The Minerovic et al patent is a proper 103 (a) reference.

With regard to the amended claim 1, "releasing the composition when the package is opened or when the composition dissolves and passes through a porous



portion of the package". Minerovic et al teaches that the package is opened (figure 2, 40) and the composition dissolves (col.7, lines 8-9) and passes through a porous portion of the package (col.5, lines 66-67).

With regard to the amended claims 4, 6, 8, 15, 19, and 21, all the concepts are covered in the office action mentioned above.

With regard to the new added claim 22, all the concepts are covered in the office action mentioned above.

With regard to the drawings, they are approved. A copy of PTO 948 is included.

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1744

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-7719 for After Final communications.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji *MRC*  
Patent Examiner  
AU 1744  
June 27, 2001

*Robert J. Warden, Sr.*  
ROBERT J. WARDEN, SR.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700